Data Evaluation Report on the terrestrial field dissipation of Fenamidone

PMRA Submission Number {.....} EPA MRID Number 45385905

Data Requirement: PMRA Data Code:
EPA DP Barcode: D275213
OECD Data Point:
EPA Guideline: 164-1

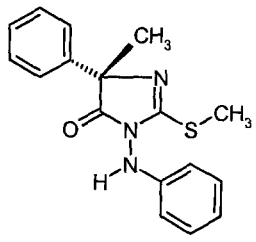
Test material: RPA 407213

End Use Product name: EXP 10623A **Concentration of a.i.** 500 g/L

Formulation type: Suspendable Concentrate

Active ingredient
Common name: Fenamidone
Chemical name
IUPAC: (+)-(4*S*)-4-Methyl-2-methylthio-4-phenyl-(1H)-1-phenylamino-2-imidazolin-5-one.
CAS name: 4*H*-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (*S*)-.
CAS No: 161326-34-7.
Synonyms: Reason 500 SC Fungicide.
Methyl-2-methylthio-5-phenyl-3-phenylamino-3,5-dihydro-4H-imidazol-4-one.
(*S*)-1-Anilino-4-methyl-2-methylthio-4-phenylimidazolin-5-one.
(*S*)-5-Methyl-2-methylthio-5-phenyl-3-phenylamino-3,5-dihydroimidazol-4-one.
Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-,
(5*S*)-.
(5*S*)-3,5-Dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-4*H*-imidazol-4-one.
RPA407213.
SMILES string:

Chemical Structure:



Primary Reviewer: Dan Hunt
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Signature:
Date:

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Signed by Dynamac's reviewers on 2/25/02

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Secondary Reviewer(s): Silvia S. Termes
EPA

Signature:
Date: 24 August 2007

Company Code: [for PMRA]
Active Code: [for PMRA]
Use Site Category: [for PMRA]
EPA PC Code: 046679

CITATION: Norris, F. A. 2001. RPA 407213: Terrestrial soil dissipation under agricultural field conditions after four applications of 300 g ai/ha each. Study performed by Aventis CropScience, Research Triangle Park, NC; Plant Sciences, Inc., Watsonville; CA, Agvise, Inc., Northwood, ND; and Centre Analytical Laboratories, Inc., State College, PA. Study submitted by Aventis CropScience, Research Triangle Park, NC. Agredoc File Number B003036. Study Number 99W17535. Study initiated March 4, 1999 and completed March 15, 2001.

Administrative conclusions: This study is classified acceptable and satisfies the guideline requirement for a terrestrial field dissipation study. This study was conducted in California and fenamidone was applied 4 times at 5-day intervals

EXECUTIVE SUMMARY:

Soil dissipation/accumulation of fenamidone (RPA 407213) under US field conditions was conducted in a potato cropped plot at one site in Santa Clara County, California (Ecoregion not reported). The experiment was carried out in accordance with the U.S. EPA Pesticide Assessment Guidelines Subdivision N, 164-1 and in compliance with the U.S. EPA FIFRA (40 CFR, Part 160) Good Laboratory Practice Standards. Fenamidone was broadcast four times (5-day intervals) at 0.3 kg a.i./ha in a 16.3 x 36.1 m plot. The applied rate corresponds to 100% of the proposed label rate. Rainfall was supplemented with irrigation to reach the 30-year average rainfall. The treated plots were approximately 1 m apart at the test site. Control plots were not utilized.

The application rate was verified by the analysis of filter paper plaques that were placed in the target area and removed immediately after application. The average recoveries from the application monitors ranged from 42.0-57.0% of the theoretical application rate, based on the four field applications. Field spiking of the samples was not performed.

Soil samples were taken following each of the four applications and at 3, 6, 14, 20, 27, 55, 93, 114, 154, and 182 days posttreatment of the last application. All samples were taken to a depth of 90 cm except for samples collected immediately following the first application (15-cm depth). The soil samples were extracted with aqueous acetone, and fenamidone (RPA 407213) and its transformation products, RPA 406012, RPA 408056, RPA 409446, RPA 410914, RPA 410995 and RPA 717879, were analyzed by LC/MS/MS. The LOD and LOQ for parent and transformation products in soil were 0.003 mg/kg and 0.01 mg/kg, respectively.

At the test site, the measured zero-time concentration (following the first application) was 0.046 mg a.i./kg soil, which is 30.1% of the applied rate (reviewer-calculated based on an expected concentration of 0.153 mg a.i./kg in the 0-15 cm soil depth). Data are reviewer-calculated means of four replicates. Following the fourth application, fenamidone dissipated from a maximum of 0.192 mg a.i./kg soil at 6 days to 0.093-0.107 mg a.i./kg soil by 20-27 days and 0.032 mg a.i./kg soil by 55 days, and was last detected at 0.012 mg a.i./kg soil at 154 days posttreatment in the 0-15 cm soil layer. The only significant transformation products detected at the test site were RPA 717879 (4-methyl-4-phenylimidazolidine-2,5-dione), RPA 408056 (4-methyl-2-methylthio-4-phenyl-2-imidazolin-5-one), and RPA 406012 (5-methyl-2-methylthio-3-(4-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one), with maximum concentrations of 4.2%, 3.8%, and 3.4% of the total applied amount (0.612 mg a.i./kg soil), observed on the 93rd, 27th, and 14th day, respectively, in the 0-15 cm soil layer. Only RPA 717879 was detected at the end of the study period (182 days), at 3.1% of the total applied fenamidone in the 0-15 cm soil layer. The

residues of fenamidone and its transformation products were primarily detected in the 0-15 cm soil layer.

Under field conditions at the test site, fenamidone had a half-life value of 38.3 days. A DT90 was not determined. At the end of the 182-day period, the total carryover of residues of fenamidone was 0% of the applied amount.

A mass accounting was not calculated and non-extractable residues, volatilization, plant uptake, and run off were not measured in this study.

The major route(s) of dissipation of fenamidone under terrestrial field conditions was transformation.

RESULTS SYNOPSIS

Location/soil type: Santa Clara County, California/sandy loam soil.
Half-life: 38.3 days ($r^2 = 0.66$)
DT90: Not determined
Major transformation products detected: None
Minor transformation products detected: RPA 717879, RPA 408056, RPA 406012, RPA 410914, and RPA 409446
Dissipation routes: Transformation

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study was conducted according to U.S. EPA Pesticide Assessment Guidelines Subdivision N, 164-1. The study did not deviate from the guideline.

COMPLIANCE: The study was conducted in compliance with U.S. EPA FIFRA (40 CFR Part 160) Good Laboratory Practice Standards. Signed and dated GLP Compliance, Quality Assurance and No Data Confidentiality Claims statements were provided.

A. MATERIALS:

1. Test Material RPA 407213

Chemical Structure of the active ingredient(s):

Description: Suspendable Concentrate

Storage conditions of test chemicals: 21.9°F-93.2°F (Appendix B, p. 100)

Physico-chemical properties of the active ingredient: Fenamidone

Parameter	Values	Comments
Water solubility	0.0078 g/L	20°C
Vapour pressure/volatility	Not provided	
UV absorption	Not provided	
pKa	Not provided	
K_{ow}/log K_{ow}	640/2.8	
Stability of Compound at room temperature	Not provided	

Data were obtained from p. 14 of the study report.

2. **Test site:** The test site was located near Watsonville in Santa Clara County, California and the test plot had previously been treated with Chlorothalonil (1.5 lb a.i./A), CGA-279202 (rate was reported as confidential), and Roundup (1.5 lb a.i./A) in the previous three years (p. 17; Appendix B, Table B-4, p. 100).

Table 1: Geographic location, site description and climatic data at the study site.

Details		Test site
Geographic coordinates	Latitude	Not provided
	Longitude	Not provided
	Province/State	California
	Country	USA
	Ecoregion	Not provided
Slope Gradient		0-1%
Depth to ground water (m)		> 3 m
Distance from weather station used for climatic measurements		Precipitation was measured onsite and temperature was measured 0.25 miles from the test site
Indicate whether the meterological conditions before starting or during the study were within 30 year normal levels (Yes/No). If no, provide details.		Yes
Other details, if any		None

Data were obtained from Appendix B, Table B-2, p. 99 and Tables B-9a through B-9g, pp. 103-109 of the study report.

Table 2: Site usage and management history for the previous three years.

Use	Year	Test site
Crops grown	Previous year	Fallow
	2 years previous	Broccoli
	3 years previous	Zucchini
Pesticides used	Previous year	None
	2 years previous	Chlorothalonil
	3 years previous	CGA-279202 and Roundup
Fertilizers used	Previous year	Not provided
	2 years previous	
	3 years previous	
Cultivation methods, if provided (eg., Tillage)	Previous year	Not provided
	2 years previous	
	3 years previous	
Other details, if any	Previous year	
	2 years previous	
	3 years previous	

Data were obtained from Appendix B, Table B-4, p. 100 of the study report.

3. Soils:

Table 3: Properties of the soil from the test site.

Property	Depth (cm)					
	0-15	**15-30**	**30-45**	**45-60**	**60-75**	**75-90**
Textural classification	Sandy loam					
% sand	78	77	77	74	71	60
% silt	15	16	15	19	23	32
% clay	7	7	8	7	6	8
pH (1:1 soil:water or other)	6.4	6.4	6.2	6.3	6.4	6.4
Total organic carbon (%)	Not provided					
Total organic matter (%)	1.6	1.5	1.2	0.9	0.8	0.9
CEC (meq/100 g)	13.2	12.9	13.2	13.2	14.7	16.4
Bulk density (g/cm3)	1.30	1.27	1.25	1.21	1.19	1.14
Moisture at 1/3 atm (%)	12.0	11.7	12.5	13.2	14.9	19.2
Taxonomic classification (e.g., ferro-humic podzol)*	Coarse-loamy, mixed, superactive, thermic Cumulic Haploxerolls					
Soil mapping unit	Elder sandy loam					
Other details, if any	None					

Data were obtained from p. 22 and Appendix B, Table B-3, p. 100 of the study report.
*The taxonomic classification was obtained from the NRCS.

B. EXPERIMENTAL DESIGN:

1. Experimental design:

Table 4: Experimental design.

Details		**Test site**
Duration of study		197 days
Uncropped (bare) or cropped		Cropped
Control used (Yes/No)		No
No. of replications	Controls	N/A
	Treatments	4
Plot size (L x W m)	Controls	N/A
	Treatments	16.3 x 36.1

Details		Test site
Distance between control plot and treated plot		N/A
Distance between treated plots		40 inches
Application rates used (g a.i./ha)		300 g a.i./ha for all four applications
Was the maximum label rate per ha used in study? (Yes/No)		Yes
Number of applications		4
Application Dates (dd mm yyyy)		7/6/99, 11/6/99, 17/6/99, and 22/6/99, respectively, for applications 1-4.
For multiple applications, application rate at Day 0 and at each application time (mg a.i./kg soil)		0.153 mg a.i./kg soil for each application
Application method (eg., spraying, broadcast etc.)		Broadcast
Type of spray equipment, if used		Tractor-mounted custom built CO_2 driven sprayer with eight Tee-Jet 8002XR Flat Fan nozzles at 18 inches above the target.
Total volume of spray solution applied/plot **OR** total amount broadcasted/plot		10268-10589 ml per application
Identification and volume of carrier (e.g., water), if used		Water
Name and concentration of co-solvents, adjuvants and/or surfactants, if used		None
Indicate whether the following monthly reports were submitted: Average minimum and maximum precipitation Average minimum and maximum air temperature Average minimum and maximum soil temperature Average annual frost-free periods		 Yes (average monthly rainfall) Yes No (only mean monthly temp) No
Indicate whether the Pan evaporation data were submitted		No (evapotranspiration was provided)
Meteorological conditions during application	Cloud cover	Not provided
	Temperature (°C)	13.9, 12.8, 13.3, and 12.8, respectively for applications 1-4.
	Humidity	77%, 88%, 88%, and 100%, respectively for applications 1-4.
	Sunlight (hr)	Not provided

Details	Test site
Pesticides used during study: name of product/a.i. concentration: amount applied: application method:	 Roundup (glyphosate) 1.5 lb a.i./A (4X) Not reported
Supplemental irrigation used (Yes/No) If yes, provide the following details: No. of irrigation: Interval between irrigation: Amount of water added each time: Method of irrigation:	Yes 8 11-41 days 1.00-1.6 inches Sprinkler
Indicate whether water received through rainfall + irrigation equals the 30 year average rainfall (Yes/No)	Yes
Were the application concentrations verified? (Briefly describe in Section 2*, if used)	Yes
Were field spikes used? (Briefly describe in Section 3¶, if used)	No
Good agricultural practices followed (Yes or No)	Yes
Indicate if any abnormal climatic events occurred during the study (eg., drought, heavy rainfall, flooding, storm etc.)	None
If cropped plots are used, provide the following details: Plant - Common name/variety: Details of planting: Crop maintenance (eg., fertilizers used):	 Potato/White Rose 24 in plant spacing or 6530 plants/A None
Volatilization included in the study (Yes/No) (if included, describe in Section 4§)	No
Leaching included in the study (Yes/No) (if included, describe in Section 5ⁱ)	Yes
Run off included in the study (Yes/No) (if included, describe in Section 6¥)	No

Data were obtained from p. 17; Appendix B, Table B-2, p. 99, and Tables B-6 through B-9, pp. 103-109 of the study report.

2. Application Verification: At the test site, each application was verified by the analysis of filter paper plagues that were placed in the target area and removed immediately after application (p. 18). After the last application, the unused test substance remaining from each trial site was

returned to Rhône-Poulenc for reanalysis.

3. Field Spiking: Field spiking of the soil samples from the test site was not performed in this study.

4. Volatilization: Volatilization was not studied.

5. Leaching: At each trial site, sixteen cores (4 from each replicate plot) were taken from the treated plot up to 6 months after the last application to a depth of 90 cm (all sampling intervals except immediately following the first application) to determine the mobility of the test substance and analytes in the soil profile (p. 18).

6. Run off: Run off was not measured in this study.

7. Supplementary Study: A supplementary study was not conducted.

8. Sampling:

Table 5: Soil sampling.

Details	Test site
Method of sampling (random or systematic)	Random
Sampling intervals	Following applications 1 through 4 and at 3, 6, 14, 20, 27, 55, 93, 114, 154, and 182 days posttreatment of the last application.
Method of soil collection (eg., cores)	Cores
Sampling depth	15 cm after the first application and 90 cm after all other sampling intervals
Number of cores collected per plot	16 cores were collected from the treated plot at each sampling interval (4 cores from each of the 4 replicate plots)
Number of segments per core	One following the first application and six after all other sampling intervals
Length of soil segments	15 cm
Core diameter (Provide details if more than one width)	6.35 cm (2.5 in)
Method of sample processing, if any	The samples were collected in 15-cm increments. After sampling, all segments were composited by depth and subplot, frozen, and shipped to the analytical laboratory. Samples were then stored frozen until analysis.
Storage conditions	-25 to -8°C
Storage length (days)[1]	3-29

Data were obtained from p. 18, Table V, p. 24 and Appendix B, Table B-8, p. 102 of the study report.
[1] Storage length does not include samples that were reanalyzed for RPA 409446 and RPA 410995 following 133-232 days.

9. Analytical Procedures: Soil samples were initially analyzed for residues of fenamidone (RPA 407213) and its metabolites RPA 406012, RPA 408056, RPA 410914, and RPA 717879 and later reanalyzed to measure two additional analytes, RPA 409446 and RPA 410995 (p. 19). Soil samples were extracted twice by shaking with aqueous acetone (acetone:water, 3:1, v:v) and centrifuged. The supernatants were then decanted, filtered, and the extracts were passed through a polystyrene-divinylbenzene polymer cartridge. The analytes were eluted from the cartridge with acetonitrile. The eluate was dried and reconstituted with aqueous acetonitrile for analysis by LC/MS/MS. The limit of quantitation (LOQ) for each analyte was 0.01 mg/kg.

II. RESULTS AND DISCUSSION

1. APPLICATION MONITORS: The average recoveries from the filter paper plaques ranged from 42.0-57.0% of the theoretical application rate (Table III, p. 23; Table XII, p. 34). Reanalysis of the test substance remaining from the trial site following the last application

indicated that the product was stable under the conditions of field storage during the application period as well as during shipping and storage before and after the applications (p. 18).

2. RECOVERY FROM FIELD SPIKES: Field spiking of the samples was not performed.

3. MASS ACCOUNTING: A mass accounting was not calculated by the applicant.

Table 6. Concentration of fenamidone (RPA 407213) residues expressed as mg/kg soil, at the test site.[1]

Compound	Soil depth (cm)	Sampling times (treatment number or days following the last treatment)													
		T1	T2	T3	T4	3	6	14	20	27	55	93	114	154	182
Fenamidone	0-15	0.046	0.156	0.142	0.181	0.157	0.192	0.175	0.093	0.107	0.032	0.019	0.020	0.012	<LOQ
	15-30	NS	0.012	ND	ND	ND	<LOQ	ND	ND	ND	ND	ND	ND	ND	ND
	30-45	NS	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	45-60	NS	ND	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	60-75	NS	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	75-90	NS	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RPA 408056	0-15	ND	<LOQ	<LOQ	0.009	0.010	0.014	0.014	0.011	0.023	0.012	0.013	0.007	<LOQ	<LOQ
	15-30	NS	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	30-45	NS	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	45-60	NS	ND	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	60-75	NS	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	75-90	NS	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RPA 406012	0-15	ND	<LOQ	0.007	<LOQ	0.010	0.009	0.021	0.009	0.012	0.009	<LOQ	<LOQ	<LOQ	<LOQ
	15-30	NS	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	30-45	NS	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	45-60	NS	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	NA
	60-75	NS	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	75-90	NS	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RPA 410914	0-15	ND	ND	<LOQ	<LOQ	<LOQ	0.008	0.018	0.007	0.010	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	15-30	NS	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	30-45	NS	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	45-60	NS	ND	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Compound	Soil depth (cm)	Sampling times (treatment number or days following the last treatment)													
		T1	T2	T3	T4	3	6	14	20	27	55	93	114	154	182
	60-75	NS	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	75-90	NS	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RPA 717879	0-15	ND	ND	<LOQ	<LOQ	<LOQ	<LOQ	0.009	0.007	0.015	0.015	0.026	0.017	0.010	0.019
	15-30	NS	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	30-45	NS	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	45-60	NS	ND	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	60-75	NS	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	75-90	NS	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RPA 409446	0-15	NA	NA	NA	NA	NA	NA	0.007	NA	<LOQ	0.007	NA	<LOQ	ND	ND
	15-30	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	ND	ND
	30-45	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	ND	ND
	45-60	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	60-75	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	75-90	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RPA 410995	0-15	NA	NA	NA	NA	NA	NA	ND	NA	ND	<LOQ	NA	ND	ND	ND
	15-30	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	ND	ND
	30-45	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	ND	ND
	45-60	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	60-75	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	75-90	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Total extractable residues (if determined)		Not determined													

Compound	Soil depth (cm)	Sampling times (treatment number or days following the last treatment)												
		T1	T2	T3	T4	3	6	14	20	27	55	93	114	154	182
Total non-extractable residues (if determined)		Not determined													
Total recovery		Not determined													

1 Data are reviewer-calculated means of four replicates. In keeping with standard practice for averaging field data, the reviewer calculated the means using the value of ½ LOQ (0.005 mg/kg) for values reported as "<LOQ" and "ND" (not detected) in the data tables. Replicate data were obtained from Tables XIIIa through XIIIi, pp. 35-43 of the study report.
ND = Not Detected
NS = Not Sampled
NA = Not Analyzed

4. PARENT COMPOUND: At the test site, the measured zero-time concentration (following the first application) was 0.046 mg a.i./kg soil, which is 30.1% of the applied rate (reviewer-calculated based on an expected concentration of 0.153 mg a.i./kg in the 0-15 cm soil depth; Tables XIIIa through XIIIi, pp. 35-43). Data are reviewer-calculated means of four replicates. The reviewer calculated the means using the value of ½ LOQ (0.005 mg/kg) for values reported as "<LOQ" and "ND" (not detected) in the data tables. Fenamidone was detected at 0.046, 0.156, 0.142, and 0.181 mg a.i./kg soil following application 1 through 4, respectively, in the 0-15 cm soil layer. Fenamidone dissipated from a post final treatment maximum of 0.192 mg a.i./kg soil at 6 days to 0.093-0.107 mg a.i./kg soil by 20-27 days and 0.032 mg a.i./kg soil by 55 days, and was last detected at 0.012 mg a.i./kg soil at 154 days posttreatment in the 0-15 cm soil layer. Fenamidone was only detected once in the 15-30 cm soil layer, at 0.012 mg a.i./kg soil following the second application, and was not detected below that depth.

The reviewer-calculated half-life of fenamidone in soil under terrestrial field conditions was 38.3 days, using first-order kinetics and linear regression of the actual test substance concentrations in the 0-15 cm soil depth.

The dissipation pattern of fenamidone was linear.

5. TRANSFORMATION PRODUCTS: The transformation products detected at the test site were RPA 717879 (4-methyl-4-phenylimidazolidine-2,5-dione), RPA 408056 (4-methyl-2-methylthio-4-phenyl-2-imidazolin-5-one), RPA 406012 (5-methyl-2-methylthio-3-(4-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one), RPA 410914 ((4RS)-4-methyl-2-methylthio-(1H)-1-(2-nitrophenylamino)-4-phenyl-2-imidazolin-5-one), and RPA 409446 (5-methyl-3-(4-nitrophenylamino)-5-phenylimidazolidine-2,4-dione), with maximum concentrations of 4.2%, 3.8%, 3.4%, 2.9%, and 1.1% of the total applied amount (0.153 mg a.i./kg x 4 applications = 0.612 mg a.i./kg soil), observed on the 93rd, 27th, 14th, 14th, and 14th/55th day, respectively, in the 0-15 cm soil layer (Tables XIIIa through XIIIi, pp. 35-43). Only RPA 717879 was detected at the end of the study period (182 days), at 3.1% of the total applied fenamidone in the 0-15 cm soil layer.

Table 7: Chemical names and CAS numbers for the transformation products of Fenamidone.

Applicant's Code Name	CAS Number	CAS and/or IUPAC Chemical Name(s)	Chemical formula	Molecular weight	SMILES string
RPA 406012	451022-66-9	5-Methyl-2-methylthio-3-(4-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one		356.4	
RPA 408056	Not assigned	4-Methyl-2-methylthio-4-phenyl-2-imidazolin-5-one		220.3	
RPA 409446	Not assigned	5-Methyl-3-(4-nitrophenylamino)-5-phenylimidazolidine-2,4-dione		326.3	
RPA 410914	Not assigned	(4RS)-4-Methyl-2-methylthio-(1H)-1-(2-nitrophenylamino)-4-phenyl-2-imidazolin-5-one		356.4	
RPA 410995	Not assigned	5-methyl-3-(2-nitrophenylamino)-5-phenylimidazolidine-2,4-dione		326.3	
RPA 717879	Not assigned	4-Methyl-4-phenylimidazolidine-2,5-dione		190.2	

Data were obtained from Appendix C, pp. 136-138 of the study report.

6. EXTRACTABLE AND NON-EXTRACTABLE RESIDUES: Not applicable

Table 8: Dissipation routes of fenamidone under field conditions.

Route of dissipation	% of applied amount (at the end of study period)
Accumulation (residues) in soil/ carry over	0%
Transformation (% of transformation products)	3.1%
Leaching, if measured	Leaching was not observed
Volatilization, if measured	Volatilization was not measured
Plant uptake, if measured	Plant uptake was not measured
Run off, if measured	Run off was not measured
Total	Not determined

7. VOLATILIZATION: Volatilization was not measured.

8. PLANT UPTAKE: Plant uptake was not measured from the treated plot.

9. LEACHING: Fenamidone (RPA 407213) was only detected below the 0-15 cm soil layer once, at 0.012 mg a.i./kg soil in the 15-30 cm soil layer following the second application, and its transformation products RPA 717879, RPA 408056, RPA 406012, RPA 410914, and RPA 409446 were not detected below the 15-cm soil layer at any sampling intervals (Tables XIIIa-XIIIi, pp. 35-43).

10. RUN OFF: Run off was not measured.

11. RESIDUE CARRYOVER: After 182 days, 0% of the applied parent compound was detected in the test plot and has no potential to carryover into the following season (Tables XIIIa-XIIIh, pp. 35-42).

12. SUPPLEMENTARY STUDY RESULTS: A supplementary study was not conducted.

III. STUDY DEFICIENCIES: The study did not deviate from Subdivision N Guideline §164-1.

IV. REVIEWER'S COMMENTS:

1. The registrant-calculated half-life of fenamidone in soil under terrestrial field conditions using the least squares best fit exponential curves was 1.42 months (p. 31, Figure 1, p. 44). The registrant's half-life is comparable to the observed half-life and the reviewer-calculated half-life of 38.3 days ($r^2 = 0.66$). The reviewer-calculated half-life was calculated with Microsoft Excel 2000 using first-order kinetics and linear regression of the actual test substance concentrations in the 0-15 cm soil depth (all replicate data) as provided by the registrant in Tables XIIIa-XIIIh (pp. 35-42).

2. A control plot was not established and sampled at the test site.

3. Pan evaporation data were not reported for the test site. However, evapotranspiration data was reported for the test site (Tables B-9a to B-9g, pp. 103-109).

4. The potatoes were not analyzed for residues of fenamidone.

5. Frozen storage stability data were reported in a prior study (MRID 45385904) utilizing soil from the test site. Data indicated that fenamidone (RPA 407213) is not stable in frozen storage. However, the reviewer notes that samples analyzed for fenamidone were stored frozen for a maximum of 29 days after sampling. The metabolites RPA 406012, RPA 408056, RPA 409446, RPA 410914, RPA 410995 and RPA 717879 were all observed to be stable in soil samples while stored frozen for up to 12 months.

6. Fenamidone chemical names (*S*)-1-anilino-4-methyl-2-methylthio-4-phenylimidazolin-5-one and (5S)-3,5-dihyro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-4H-imidazol-4-one were identified as the IUPAC and CAS names, respectively, by the Compendium of Pesticide Common Names (http://www.hclrss.demon.co.uk/index.html).

V. REFERENCES: The following references were cited in the study:

1. Pesticide Assessment Guidelines, Subdivision N. 1982. Chemistry: Environmental Fate §164.1. United States Environmental Protection Agency [EPA-540-982-021]. Washington, DC.

2. Standard Evaluation Procedure for Terrestrial Field Dissipation Studies. 1989. United States Environmental Protection Agency [PB-90-208935]. Washington, DC.

3. Norris, F.A. 15 March 2001. "RPA 407213: Terrestrial Field Dissipation Under Agricultural Field Conditions." Rhône-Poulenc Ag Co. Study 98W13195, Aventis CropScience Document B003033.

4. Simmonds, M. B., and Burr, C. M. 4 January 1999. "[^{14}C]-RPA 407213: Route of Degradation in Soil" Rhône-Poulenc Agro Document No. 201609.

5. Simmonds, M. B., and Burr, C. M. 12 March 1999. "[^{14}C]-RPA 407213: Rate of Aerobic Degradation in Three Soil Types at 20°C and One Soil Type at 10°C." Rhône-Poulenc Agro Document No. 201610.

6. Wicks, R. J. 28 July 1999. "RPA 407213: Field Soil Dissipation Study in Europe" Rhône-Poulenc Agro Document No. 202140.

7. Hunt, T. W. 16 October 1996. "Outliers-Determination and Handling" Rhône-Poulenc Ag Company SOP 25932.

Attachment 1

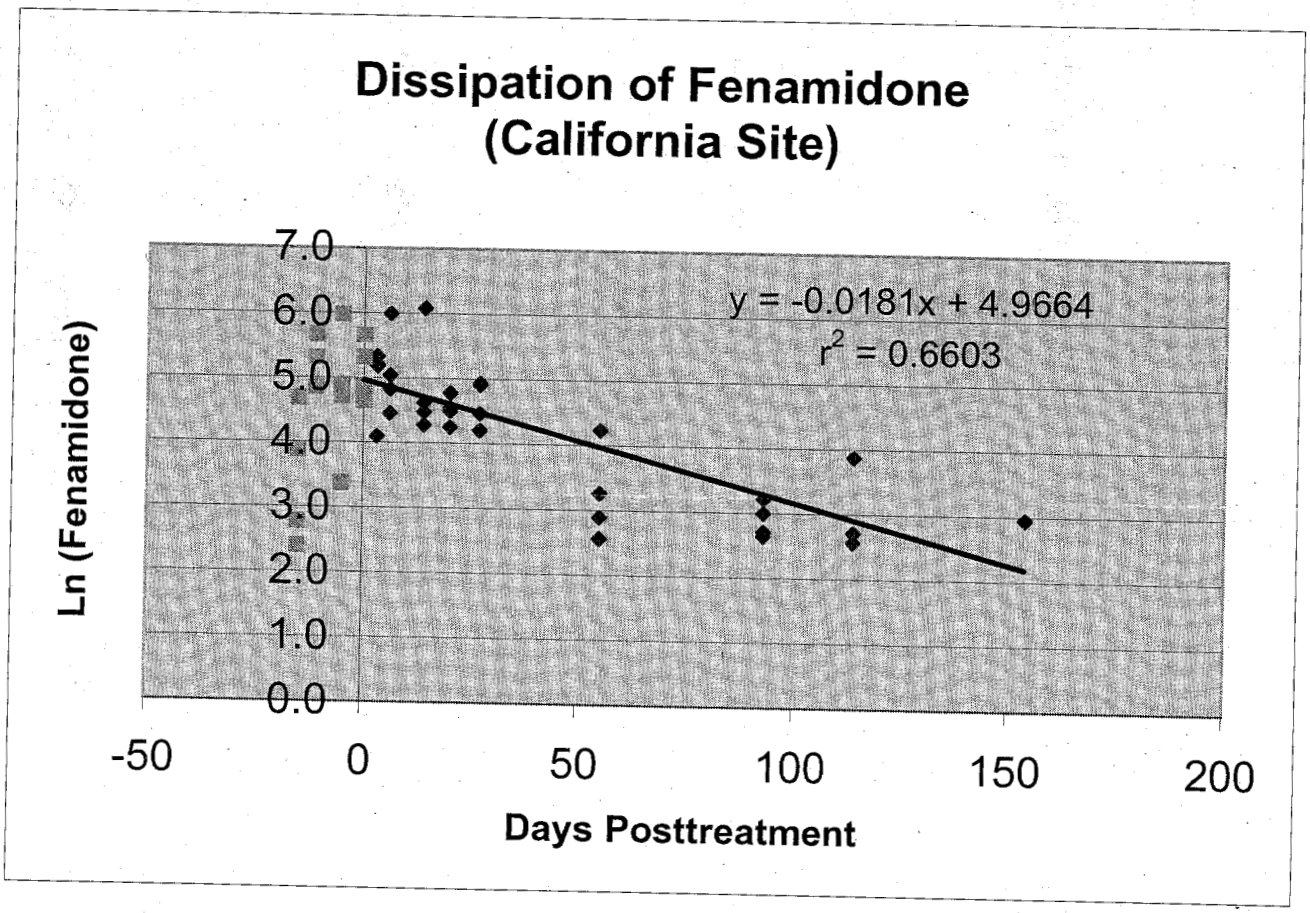
Excel Spreadsheets

Chemical Name	Fenamidone	**California Site**
PC Code	046679	**0-15 cm soil depth**
MRID	45385905	
Guideline No.	164-1	

Half-life (days) = 38.3

Days Posttreatment	Fenamidone (ug/kg)	Ln (Fenamidone)
Application 1 (-15 days)	16	2.7726
Application 1 (-15 days)	11	2.3979
Application 1 (-15 days)	108	4.6821
Application 1 (-15 days)	48	3.8712
Application 2 (-11 days)	ND	
Application 2 (-11 days)	128	4.8520
Application 2 (-11 days)	202	5.3083
Application 2 (-11 days)	289	5.6664
Application 3 (-5 days)	111	4.7095
Application 3 (-5 days)	134	4.8978
Application 3 (-5 days)	29	3.3673
Application 3 (-5 days)	395	5.9789
Application 4 (day 0)	104	4.6444
Application 4 (day 0)	286	5.6560
Application 4 (day 0)	131	4.8752
Application 4 (day 0)	204	5.3181
3	207	5.3327
3	183	5.2095
3	179	5.1874
3	60	4.0943
6	125	4.8283
6	155	5.0434
6	86	4.4543
6	401	5.9940
14	88	4.4773
14	102	4.6250
14	72	4.2767
14	437	6.0799
20	119	4.7791
20	70	4.2485
20	94	4.5433
20	90	4.4998
27	87	4.4659
27	136	4.9127
27	139	4.9345
27	67	4.2047
55	26	3.2581
55	13	2.5649
55	69	4.2341
55	18	2.8904
93	15	2.7081
93	14	2.6391

Days Posttreatment	Fenamidone (ug/kg)	Ln (Fenamidone)
93	25	3.2189
93	20	2.9957
114	48	3.8712
114	<LOQ	
114	13	2.5649
114	15	2.7081
154	<LOQ	
154	19	2.9444
154	19	2.9444
154	ND	
182	<LOQ	
182	<LOQ	
182	<LOQ	
182	ND	



Attachment 2

Structures of Parent and Transformation Products

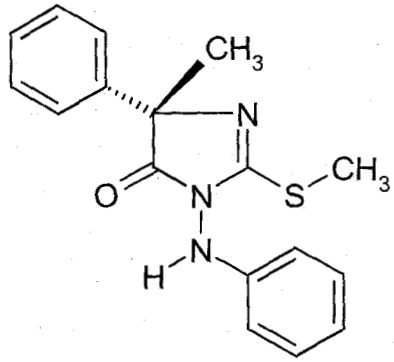
RPA 407213

IUPAC name: (*S*)-5-Methyl-2-methylthio-5-phenyl-3-phenylamino-3,5-dihydroimidazol-4-one
(*S*)-4-Methyl-2-methylthio-4-phenyl-1-phenylamino-5(4H)-imidazolone

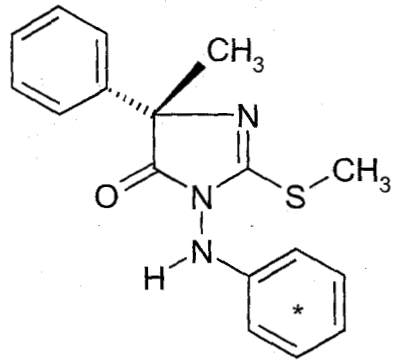
CAS name: 4*H*-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (S)-

CAS #: 161326-34-7

Unlabelled



With radiolabel



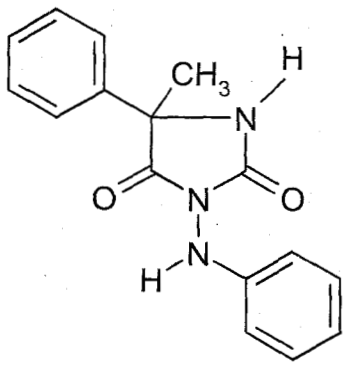
*Position of [^{14}C]-radiolabel

RPA 405862

IUPAC name: 5-Methyl-5-phenyl-3-phenylaminoimidazolidine-2,4-dione

CAS name: 2,4-Imidazolidinedione, 5-methyl-5-phenyl-3-(phenylamino)-

CAS #: 153969-11-0

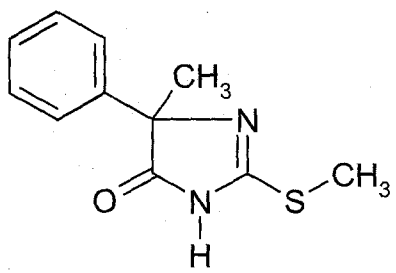


RPA 408056

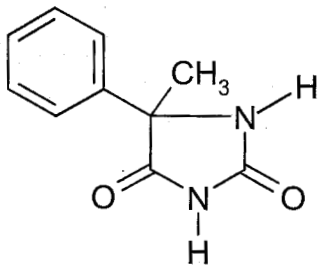
IUPAC name: 5-Methyl-2-methylthio-5-phenyl-3,5-dihydroimidazol-4-one
4-Methyl-2-methylthio-4-phenyl-2-imidazolin-5-one

CAS name: 4*H*-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-

CAS #: N/A



RPA 717879
IUPAC name: 5-Methyl-5-phenylimidazolidine-2,4-dione
CAS name: 2,4-Imidazolidinedione, 5-methyl-5-phenyl-
CAS #: 6843-49-8

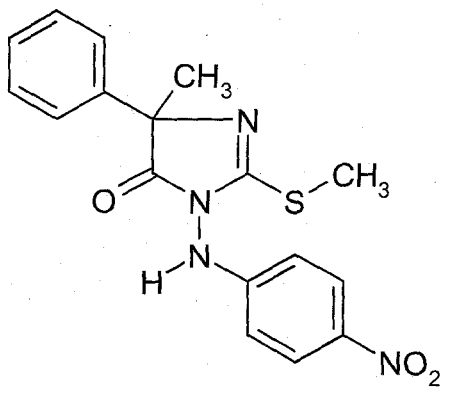


RPA 406012

IUPAC name: 5-Methyl-2-methylthio-3-(4-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one

CAS name: 4*H*-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-3-[(4-nitrophenyl)amino]-5-phenyl-

CAS #: 151022-56-9
451022-66-9

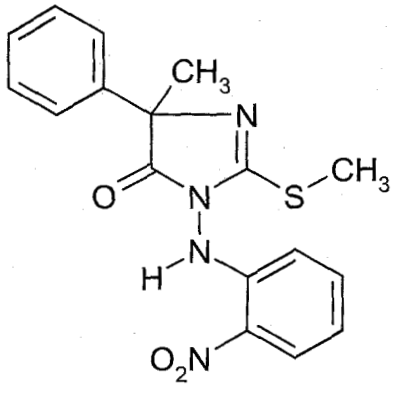


RPA 410914

IUPAC name: 5-Methyl-2-methylthio-3-(2-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one
(4RS)-4-methyl-2-methylthio-(1H)-1-(2-nitrophenylamino)-4-phenyl-2-imidazolin-5-one

CAS name: 4*H*-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-3-(2-nitrophenylamino)-5-phenyl-

CAS #: N/A

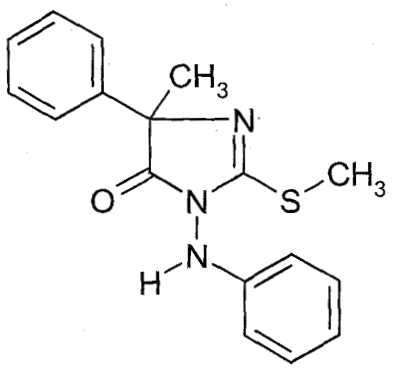


RPA 405803

IUPAC name: 5-Methyl-2-methylthio-5-phenyl-3-phenylamino-3,5-dihydroimidazol-4-one

CAS name: 4*H*-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-

CAS #: 151022-37-6

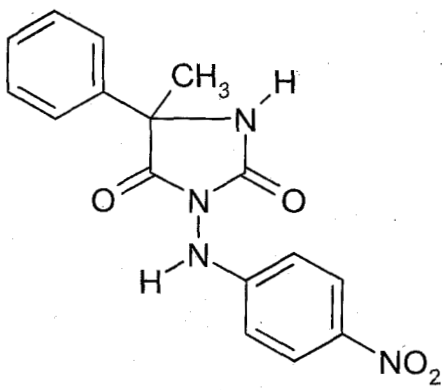


RPA 409446

IUPAC name: 5-Methyl-3-(4-nitrophenylamino)-5-phenylimidazolidine-2,4-dione

CAS name: 2,4-Imidazolidinedione, 5-methyl-3-(4-nitrophenylamino)-5-phenyl-

CAS #: N/A

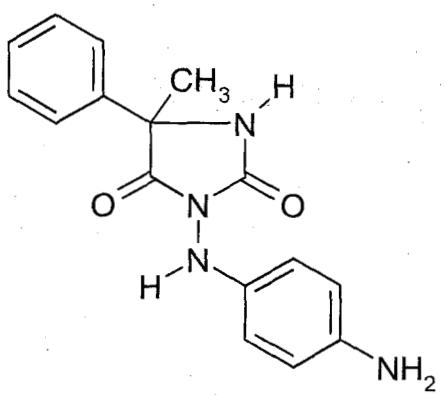


RPA 409445

IUPAC name: 3-(4-Aminophenylamino)-5-methyl-5-phenylimidazolidine-2,4-dione

CAS name: 2,4-Imidazolidinedione, 3-(4-aminophenylamino)-5-methyl-5-phenyl-

CAS #: N/A

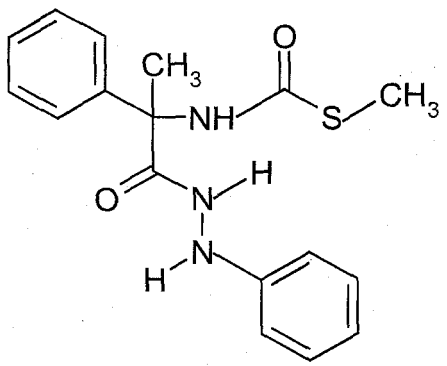


RPA 407599

IUPAC name: [1-Phenyl-1-(N'-phenylhydrazinocarbonyl)-ethyl]-thiocarbamic acid S-methyl ester

CAS name: Benezeneacetic acid, α-methyl-N-thiocarboxy-, S-methyl ester, 2-phenylhydrazide

CAS #: N/A

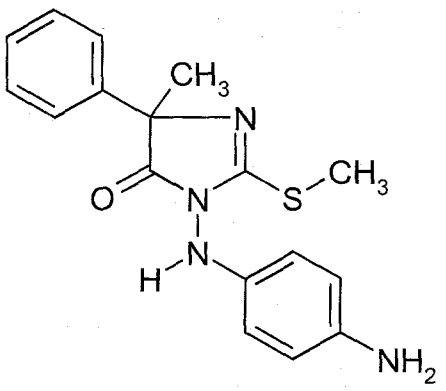


RPA 409352

IUPAC name: 3-(4-Aminophenylamino)-5-methyl-2-methylthio-5-phenyl-3,5-dihydroimidazol-4-one

CAS name: 4*H*-Imidazol-4-one, 3,5-dihydro-3-(4-aminophenylamino)-5-methyl-2-(methylthio)-5-phenyl-

CAS #: N/A

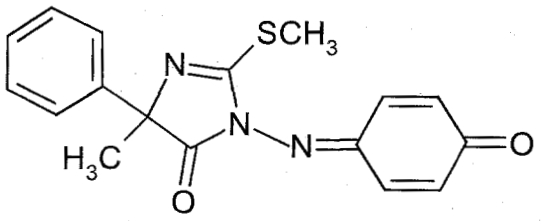


RPA 418915

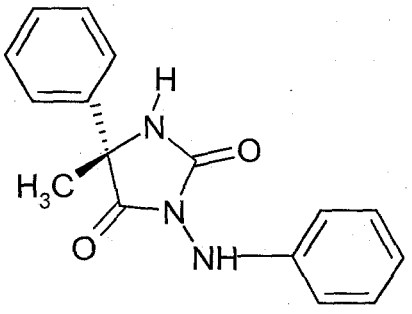
IUPAC name: (*S*)-5-Methyl-2-methylthio-3-[4-oxo-2,5-cyclohexadien-1-ylidene)amino]-5-phenyl-3,5-dihydroimidazol-4-one

CAS name: N/A

CAS #: N/A



RPA 410193
IUPAC name: (*S*)-4-Methyl-4-phenyl-1-phenylaminoimidazolidin-2,5-dione
CAS name: N/A
CAS #: N/A

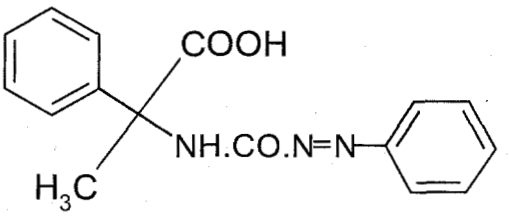


RPA 409344

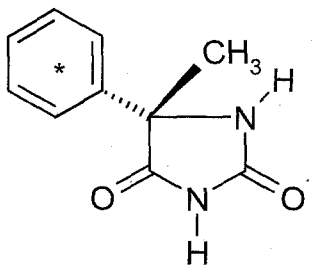
IUPAC name: (R,S)-2-methyl-2-phenyl-N-(phenylazocarbonyl)glycine
(R,S)-2-phenyl-2-(phenylazocarbonylamino)propionic acid

CAS name: N/A

CAS #: N/A



RPA 412636
IUPAC name: (*S*)-5-Methyl-5-phenylimidazolidine-2,4-dione
CAS name: 2,4-Imidazolidinedione,5-methyl-5-phenyl-, (S)
CAS #: 27539-12-4



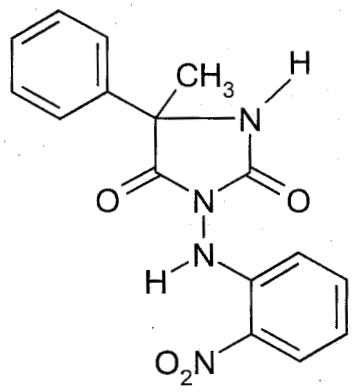
* Position of [^{14}C] radiolabel

RPA 410995

IUPAC name: 5-Methyl-3-(2-nitrophenylamino)-5-phenylimidazolidine-2,4-dione

CAS name: 2,4-Imidazolidinedione, 5-methyl-3-[(2-nitrophenyl)amino]-5-phenyl-

CAS #: N/A

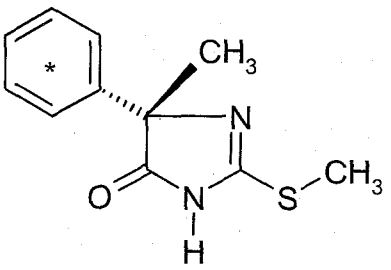


RPA 412708

IUPAC name: (*S*)-5-Methyl-2-methylthio-5-phenyl-3,5-dihydroimidazol-4-one

CAS name: 4*H*-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-,(S)-

CAS #: N/A

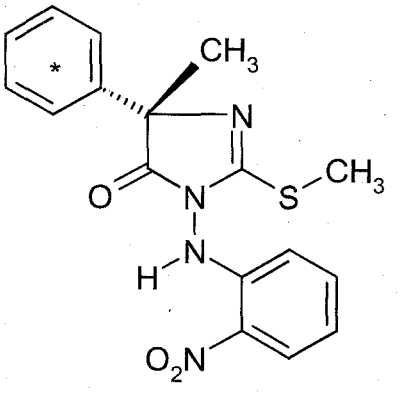


RPA 413255

IUPAC name: (*S*)-5-Methyl-2-methylthio-3-(2-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one

CAS name: 4*H*-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-3-(2-nitrophenylamino)-5-phenyl-,(S)-

CAS #: N/A



* Position of [^{14}C] radiolabel

Attachment 3

Transformation Pathway Presented by Registrant
Figure of Dissipation of Fenamidone in Test Soil

Metabolism of Fenamidone in Soil

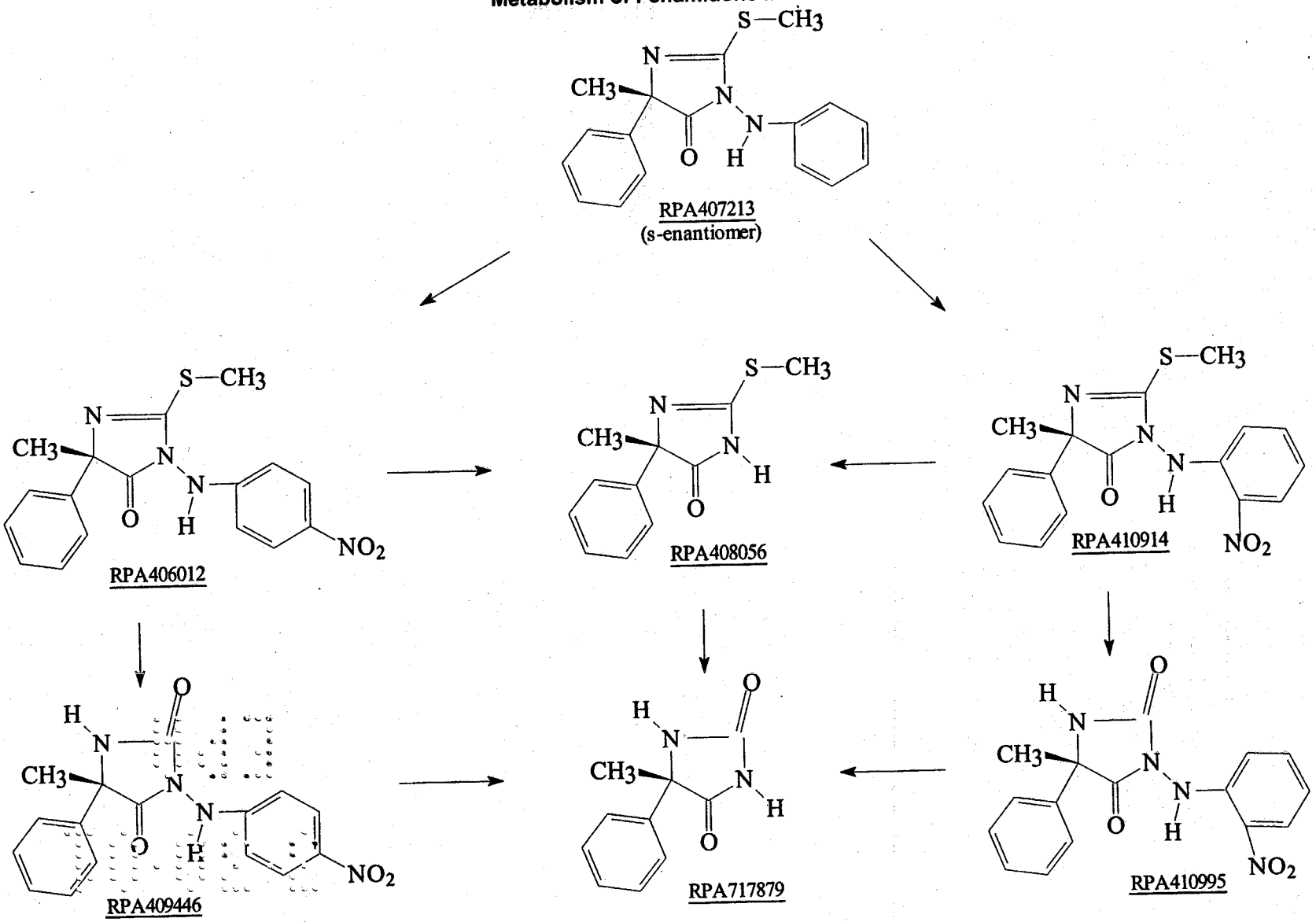


Figure 1. DISSIPATION OF FENAMIDONE IN A CALIFORNIA SOIL